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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/742,096	12/22/2000	Pierre Druille	200773US0DIV	7658
22850	7590	12/03/2004		
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER GRUN, JAMES LESLIE	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/742,096	Applicant(s) DRUILHE ET AL.	
	Examiner James L Grun	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-55 is/are pending in the application.
- 4a) Of the above claim(s) 30-34, 36-38, 40-42, 45-47 and 49-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-29, 35, 39, 43, 44 and 48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

The amendment filed 03 September 2004 is acknowledged and has been entered. Claim 55 is newly added. Claims 1-26 have been cancelled. Claims 27-55 remain in the case. Claims 27-29, 35, 39, 43, 44, and 48 are under examination.

Newly submitted claim 55 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the originally claimed invention, related to the newly presented invention of claim 55, are related as subcombinations usable together in a single combination which are distinct from each other by being separately usable as evidenced by the invention as originally claimed. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 55 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Claims 30-34, 36-38, 40-42, 45-47, and 49-55 have been withdrawn from further consideration as being drawn to a non-elected invention.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 27-29, 35, 39, 43, 44, and 48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the invention as is now claimed. The specification, as originally filed, does not provide support for exclusion of “**all or part** of one or more polypeptides” (emphasis added) as is now recited. For example the specification teaches that other fragments, either longer or shorter, included or combined with the previously recited fragments form part of the invention (see e.g. page 5). If applicant originally intended “all or part”, as is now recited, there would seem to have been no need to separately list fragments wholly contained within other of the recited fragments for exclusion. Applicant is requested to direct the Examiner's attention to specific passages where support for this newly recited limitation can be found in the specification as filed or is required to delete the new matter.

The specification is objected to and claims 27-29, 35, 39, 43, 44, and 48 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons of record that the specification contains subject matter which was not described in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and which was not described in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As set forth, absent any guidance to those peptides, other than those peptides which have been excluded, which predictably function for any given purpose in the invention, extensive random unpredictable experimentation would be required to determine useable peptide molecules for any given purpose. Moreover, the specification lacks adequate description and enablement of the invention as instantly claimed because the sequence designated in claim 27 as “(729S)” (SEQ ID NO: 11) is not found by the examiner in the sequence of Fig. 2 (i.e. SEQ ID NO: 3). One would

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be unable to practice the invention as instantly claimed because one would be unable to exclude that which does not exist.

Applicant's arguments filed 03 September 2004 have been fully considered but they are not deemed to be persuasive. Applicant urges that the sequence of SEQ ID NO: 11 is found in instant Fig. 2 and in Fig. 3 of U.S. Pat. No. 6,319,502. This is not found persuasive because, notwithstanding applicant's assertions to the contrary, instant SEQ ID NO: 11, as originally disclosed in the instant application, is not found in the sequences that applicant cites.

Applicant's attention is drawn to "VEENVEENVENNDDGSVA" (emphasis added) set forth as an original part of instant SEQ ID NO: 11. Applicant urges that 2 recombinant peptides which, together with the 729 peptide, cover 95% of the LSA-3 molecule were tested in the instant examples and that one of them, GST-3PC which spans amino acid residue 869 to presumably amino acid residue 1786 (see e.g. page 34), elicited antibodies in mice. This is not found persuasive because a polypeptide encompassing approximately half of the protein does not guide one to peptides of 10-50 amino acid residues which predictably function for any given purpose in the invention. Applicant urges that further experiments, detailed in the summary provided as Annex I with the instant response, demonstrated the human antigenicity of various LSA-3 peptides. This would support the examiner's reasons of record that further random unpredictable experimentation, unguided by applicant's specification, was necessary at the time of filing in order to identify usable peptides other than those excluded by the claims. The rejection is maintained.

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Claims 27-29, 35, 39, 43, 44, and 48 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 27 and claims dependent thereupon, the metes and bounds of the polypeptide molecule for which applicant desires protection is not clear. For example, it is not clear if a shorter peptide, comprising at least 10 amino acid residues, which excludes part and includes part of one of the recited sequences is excluded or included. Likewise, it is not clear if a longer peptide which fully encompasses one of the recited sequences is excluded or included.

In claim 35, multiple elements lack antecedent basis, i.e. "the" reaction, antigen/antibody complexes, and immunological reaction all lack antecedent basis. This claim is vague and indefinite as to how many or what kind of reagents or reactions are intended, or what relationship any of the components bear to any of the other assay components.

Applicant's arguments filed 03 September 2004 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's urgings to the contrary, applicant's amendments have not obviated the prior rejections for the reasons set forth above.

Claims 27-29 are rejected under 35 U.S.C. § 102(a) as being clearly anticipated by Barnes et al. (Exp. Parasitol. 81: 79-89, August 1995) for reasons of record.

Applicant's arguments filed 03 September 2004 have been fully considered but they are not deemed to be persuasive. As set forth, applicant cannot rely upon the foreign priority claim to overcome this rejection because the requirements of 35 U.S.C. § 119 have not been met in

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either the parent application (see Form PCT/DO/EO/903 therein) or in the instant application.

The certified copy of the priority document is absent.

Claims 27-29, 35, 39, and 43 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter for reasons of record.

Claims 27-29, 35, 39, and 43 are rejected under 35 U.S.C. § 102(b) as being anticipated by Guerin-Marchand et al. (WO 92/13884) in light of the translation provided in Guerin-Marchand et al. (U.S. Pat. No. 6,270,771) for reasons of record.

Claims 27-29, 35, 39, and 43 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Guerin-Marchand et al. (U.S. Pat. No. 6,319,502) for reasons of record.

Applicant's arguments filed 03 September 2004 have been fully considered but they are not deemed to be persuasive. Applicant urges that the claims are concerned with the entire LSA-3 sequence. This is not found persuasive because the claims are drawn to peptides of at least 10 amino acid residues, not the entire sequence. Applicant urges that the references teach partial LSA-3 sequences excluded by the claims. This is not found persuasive because, for the reasons of record, the references do not teach only excluded sequences. The discussion herein above of what is included or excluded by the claims under 35 U.S.C. § 112, second paragraph, is noted and incorporated herein. The discussion herein above of the excluded sequence instantly identified as "729S" under 35 U.S.C. § 112, first paragraph, which is different and shorter than the peptide described by the references, is noted and incorporated herein. Applicant urges that the common inventor of the instant application and the references contributed to the invention.

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This is not in dispute. However, the invention as claimed is fully disclosed by an inventive entity different from that of the instant application. The rejections are maintained.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR REPLY TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE MAILING DATE OF THIS ACTION. IN THE EVENT A FIRST REPLY IS FILED WITHIN **TWO MONTHS** OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE **THREE-MONTH** SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR REPLY EXPIRE LATER THAN **SIX MONTHS** FROM THE MAILING DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

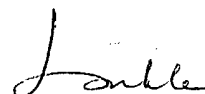
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone numbers for official facsimile transmitted communications to TC 1600, Group 1640, are (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.



James L. Grun, Ph.D.
November 23, 2004



LONG V. LE
SUPERVISORY PATENT EXAMINER
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11/27/04